BIOENGINEERING RESEARCH PARTNERSHIPS

RELEASE DATE: November 20, 2002

PA NUMBER: PAR-03-032

APPLICATION RECEIPT DATES: January 23, 2003 and August 22, 2003

NOTICE OF INTENT RECEIPT DATES: December 20, 2002 and July 22, 2003

EXPIRATION DATE: August 23, 2003, unless re-issued

National Cancer Institute (NCI)
(http://www.nci.nih.gov)
National Eye Institute (NEI)
(http://www.nei.nih.gov)
National Heart, Lung, and Blood Institute (NHLBI)
(http://www.nhlbi.nih.gov)
National Human Genome Research Institute (NHGRI)
(http://www.nhgri.nih.gov)
National Institute on Aging (NIA)
(http://www.nia.nih.gov)
National Institute of Allergy and Infectious Diseases (NIAID)
(http://www.niaid.nih.gov)
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
(http://www.niams.nih.gov)
National Institute of Biomedical Imaging and Bioengineering (NIBIB)
(http://www.nibib.nih.gov)
National Institute of Child Health and Human Development (NICHD)
(http://www.nichd.nih.gov)
National Institute on Drug Abuse (NIDA)
(http://www.nida.nih.gov)
National Institute on Deafness and Other Communication Disorders (NIDCD)
(http://www.nidcd.nih.gov)
National Institute of Dental and Craniofacial Research (NIDCR)
(http://www.nidcr.nih.gov)
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

(http://www.niddk.nih.gov)
National Institute of Environmental Health Sciences (NIEHS)
(http://www.niehs.nih.gov)
National Institute of General Medical Sciences (NIGMS)
(http://www.nigms.nih.gov)
National Institute of Neurological Disorders and Stroke (NINDS)
(http://www.ninds.nih.gov)
National Library of Medicine (NLM)
(http://www.nlm.nih.gov)

THIS PA CONTAINS THE FOLLOWING INFORMATION

PURPOSE OF THIS PA

Participating Institutes and Centers (ICs) of the National Institutes of Health (NIH) invite applications for R01 awards to support Bioengineering Research Partnerships (BRPs) for basic and applied multi-disciplinary research that addresses important biological or medical research problems. A BRP is a multi-disciplinary research team applying an integrative, systems approach to develop knowledge and/or methods to prevent, detect, diagnose, or treat disease or to understand health and behavior. The partnership must include appropriate bioengineering or allied quantitative sciences in combination with biomedical and/or clinical investigators. A BRP may propose design-directed, developmental, discovery-driven, or hypothesis-driven research at universities, national laboratories, medical schools, large or small businesses, or other public and private entities or combinations of these entities.

On October 11, 2001, NIH issued a related program announcement (PA) PA-02-011 for Bioengineering Research Grants (BRGs). The BRGs differ from the BRPs in that the BRG research will be performed in a single laboratory or by a small number of investigators.

RESEARCH OBJECTIVES

Many of today's biomedical problems are best addressed using a multi-disciplinary approach that extends beyond the traditional biological and clinical sciences. Bioengineering integrates principles from a diversity of technical and biomedical fields and crosses the boundaries of many scientific disciplines represented throughout academia, laboratories, and industry. The creativity of interdisciplinary teams is resulting in new basic understandings, novel products, and innovative technologies for addressing biomedical problems.

Recognizing the importance of bioengineering in public health, the Bioengineering Consortium (BECON) was established in 1997 as a focus for bioengineering activities at the NIH. To facilitate communication between the allied and biomedical disciplines and to provide input from the scientific community on research needs and directions, the BECON has held annual two-day symposia on emerging topics of interest related to bioengineering including bioengineering (1998), bioimaging, (1999), nanotechnology (2000), reparative medicine (2001), and biosensors (2002). Summaries of the proceedings and recommendations of these symposia are available on the Internet at http://www.becon.nih.gov/becon_symposia.htm.

Discussions and recommendations of symposia participants aided the formulation of the BRP and BRG program announcements. Both the BRP and BRG PAs recognize that applications for bioengineering projects often focus on technology development rather than on proving or disproving scientific hypotheses. Therefore, the NIH review criteria for bioengineering applications submitted in response to these PAs have been modified to ensure that these proposals are evaluated appropriately and fairly.

One objective of this program announcement is to encourage basic and applied bioengineering research that could make a significant contribution to improving human health. Bioengineering integrates physical, engineering, and computational science principles for the study of biology, medicine, behavior, or health. It advances fundamental concepts, creates knowledge from the molecular to the organ systems level, and develops innovative biologicals, materials, processes, implants, devices, and informatics approaches for the prevention, diagnosis, and treatment of disease, for patient rehabilitation, and for improving health.

A second objective is to encourage collaborations and partnerships among the allied quantitative and biomedical disciplines. A BRP should bring together necessary physical, engineering, or computational science expertise with biological or clinical resources to address a significant area of bioengineering research within the mission of the NIH. In addition to the benefits to be derived from the research, the collaborations and partnerships can create opportunities for trans-disciplinary communication and training for a new generation of scientists capable of interacting across traditional technical boundaries.

Applications for a BRP award should focus on an area of basic, applied, behavioral, or clinical research in bioengineering that supports the missions of the NIH institutes and centers and where progress is likely to make a significant contribution to improving human health. Some NIH institutes and centers have indicated that they will only consider BRP applications in specific focus areas. These institutes and focus areas are available at http://www.becon.nih.gov/becon_brpareas.htm

MECHANISM OF SUPPORT

The mechanism of support is the NIH R01 research grant. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant.

The initial period of support of a BRP award may be up to five years. The award may be competitively renewed for a second period up to five years. If competing segments of a BRP award are shorter than five years, grantees may apply for more than one renewal but for no more than ten years total of NIH funding. Competing renewal and revised applications for BRP grants are to be received at the NIH on the same receipt dates as new BRP applications.

Since it is expected that applications will request over $250,000 detailed budgets will need to be submitted.

FUNDS AVAILABLE

For new grants, the maximum total (direct plus facilities and administrative (F&A) costs)- cost to be awarded in any year is $2 million. This limit does not apply to competing continuation applications. The number of awards and level of support will depend on the number of applications of high scientific merit that are received and the availability of funds. Funding in subsequent years will be contingent upon satisfactory progress during the preceding year(s) and

the availability of funds. Applicants are encouraged to discuss budget requests with NIH scientific and financial contacts listed under WHERE TO SEND INQUIRIES prior to submission.

Grantees have the authority to extend the duration of a BRP grant on a no-cost basis. This extension provides additional time to use funds that remain available at the end of the project period to continue pursuing the aims of the grant. Grantees should notify the Grants Management Officer of the awarding institute or center of the no-cost extension as early as possible and before the expiration of the grant.

ELIGIBLE INSTITUTIONS

You may submit (an) application(s) if your institution has any of the following characteristics:

o Domestic for-profit or non-profit organizations
o Domestic public or private institutions, such as universities, colleges, hospitals, and national laboratories
o Units of State and local governments
o Eligible agencies of the Federal government
o Large or small businesses
o Faith-based or community-based organizations

Foreign institutions are not eligible to apply. However, BRP collaborative projects may include work at a foreign site when the expertise at the foreign site is not present in the United States. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as principal investigators.

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

SPECIAL REQUIREMENTS

SPECIFIC INSTRUCTIONS FOR APPLICATIONS REQUESTING $500,000 OR MORE PER YEAR:

Applicants requesting $500,000 or more in direct costs for any year must receive permission to submit the application six weeks before the submittal deadline (December 11, 2002, and July 11, 2003, for this PA) and must identify the NIH staff member within one of NIH institutes or centers who has agreed to accept assignment in the cover letter that transmits the application.

BRP applicants for projects with direct costs exceeding $500,000 in any year must carry out the following steps:

1) At least six weeks before submitting the application (i.e., as you are developing plans for the study), contact a program staff member from an IC which may be appropriate for supporting the project based on its mission to request approval to submit the application. A list of scientific program contacts for participating IC's is available on the Internet at http://www.becon.nih.gov/becon_contacts.htm,

2) Obtain agreement from the IC staff member that the IC will accept your application for consideration for award, and,

3) Identify the staff member and IC who agreed to accept assignment of the application in the cover letter that transmits the application.

This policy applies to all investigator-initiated new (type 1), competing continuation (type 2), competing supplement, or any amended or revised version of these grant application types. Additional information on this policy is available in the NIH Guide for Grants and Contracts, October 19, 2001, at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html.

NOTICE OF INTENT: Prospective applicants are asked to submit a letter of intent that includes the following information:

o Descriptive title of the proposed research
o Name, address, and telephone number of the Principal Investigator
o Names of other key personnel
o Participating institutions
o Number and title of this PAR

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed at the beginning of this document. The letter of intent should be sent to:

Dr. Richard E. Swaja
National Institute of Biomedical Imaging and Bioengineering
6707 Democracy Boulevard
Bethesda, MD 20892-5469
Telephone: (301) 451-4779
FAX: (301) 480-4973
Email: noi@nibib.nih.gov

BRP ORGANIZATIONAL STRUCTURE, LEADERSHIP, AND MANAGEMENT: An organizational structure that clearly defines the partnership and justifies relationships among the various components must be developed and described in the application. The BRP size, structure, and mode of operation should match the needs and scope of the proposed research. The BRP Principal Investigator (PI) is responsible for management, staffing, and resource allocation and for administering the award in accordance with NIH policies. The PI has the responsibility and authority to use BRP funds in the most productive way to achieve the goals defined at the time of the award. To accomplish this task, the PI can adjust funding among BRP participants to support new partners or to reduce support to old partners as needed.

BRP PI MEETING: BRP PIs will meet annually in Bethesda, Maryland, to share results, to ensure that the NIH has a coherent view of the advances in these fields, and to have an opportunity for collective problem solving among the PIs. The cost of participating in this annual meeting should be included in the BRP budget.

WHERE TO SEND INQUIRIES

We encourage inquiries concerning this PA and welcome the opportunity to answer questions from potential applicants.

Inquiries or contacts concerning institute-specific scientific or financial issues should be directed to the NIH BECON scientific or financial contacts listed at the following Web site:

http://www.becon.nih.gov/becon_contacts.htm. These scientific contacts can also be used to obtain permission to submit applications that request more the $500,000 of direct costs in any year.

Inquiries regarding general BRP programmatic issues should be directed to:

Dr. Richard E. Swaja
National Institute of Biomedical Imaging and Bioengineering/NIH/DHHS
6707 Democracy Boulevard – Suite 200
Bethesda, MD 20892-5469
TEL: 301-451-4779
FAX: 301-480-4973
E-mail: swajar@nibib.nih.gov

Inquiries concerning BRP review issues should be directed to:

Dr. Eileen Bradley
Center for Scientific Review/NIH/DHHS
6701 Rockledge Drive
Bethesda, MD 20892
TEL: 301-435-1179
FAX: 301-480-2241
E-mail: bradleye@csr.nih.gov

SUBMITTING AN APPLICATION

Applicants are strongly advised to contact IC scientific program staff listed under WHERE TO SEND INQUIRIES to discuss the relevance of their proposed work to the institute's mission before preparing a detailed research application. Detailed information on research missions and programs for each NIH institute and center is available on the participating IC's Web sites which are listed at the beginning of this announcement. Some NIH institutes and centers have indicated that they will only consider BRP applications in specific focus areas. These institutes and focus areas are available at http://www.becon.nih.gov/becon_brpareas.htm

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). The PHS 398 is available at

http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

APPLICATION PREPARATION INSTRUCTIONS: Follow the PHS 398 instructions for "Preparing Your Application" with the following modifications and additions:

The title and number of this program announcement must be typed on line 2 of the face page of the application form, and the YES box must be marked.

1. Page limitations have been increased to a maximum of 40 pages from the usual 25 page limit for sections A-D of the "Research Plan" of an application. This 40 page limit is an absolute maximum. Applicants are encouraged to be concise and use fewer pages.

2. Description Page - The institution leading the BRP and any other participating institutions must be identified. The description should provide a clear indication of the area of bioengineering research that will be the focus of the BRP, the planned multidisciplinary approach, the specific milestones to be achieved, and timelines for achievement for the first year and additional years of the grant.

3. An organization chart (OC) that clearly defines the partnership and relationships among its various components must be included with the application. A program plan (PP) should accompany the OC and list major tasks with a timeline of expected milestones for the entire project period. The OC and PP must not exceed one page each. This information should be included in the Research, Design, and Methods section of the application.

4. BRP Budget Items - A separate budget for each partner at a subcontract/consortium institution, and when appropriate for clarity, for each partner within the grantee institution must be included. Include a summary budget for all BRP participants with partners at non-grantee institutions shown as consortium arrangements.

The NIH ICs will not provide annual support in excess of $2 million total cost for any year for new applications. Direct cost inflationary increases following the first year may be included, but the total cost maximum request level of $2,000,000 per year must be observed.

The PI is expected to devote a minimum of 25% effort to the BRP. The percent effort requested for other personnel should be limited to time devoted specifically to BRP Partner activities and not to other research activities.

Information documenting the level of effort on BRP activities should be included in the application. The need for all requested personnel costs should be thoroughly justified. The percent effort of the BRP PI should be justified in the context of the PI's other responsibilities. Administrative support (a secretary or an administrative assistant) may be requested for the BRP office only for matters directly pertaining to the BRP.

There will be an annual BRP PI meeting at a date and location to be determined by NIH staff. Applicants should include travel funds specifically for these meetings in the BRP budget request.

Applicants may request and justify other travel funds in addition to the funds required for the annual PI meeting. Travel funds could be used to promote collaboration among BRP partners at different institutions or at a distant site, be used for travel of external advisors to the BRP site, and/or be used for BRP partners to attend scientific meetings essential to the progress of the BRP and for which other funds are not available.

Other expenses can be requested including costs necessary for the central administration and fiscal management of the BRP including relevant and reasonable costs for reprints, graphics, and publications.

With regard to projected funding by source, some BRP applicants may anticipate or receive commitments for significant funding from other than NIH sources; e.g., from a collaborating company. In this case, applications should describe the source, annual amount, and use of the other funding.

5. Biographical Sketch – Research Support - Provide a complete listing of current and pending support for the Principal Investigator, Co-Investigator(s), and other key personnel for grantee and partnering organizations.

6. Resources - The application should describe the equipment and facilities available for the proposed BRP.

If the BRP entails an institutional commitment of resources across boundaries in the institution or anticipates the provision of institutional resources, include letters from appropriate senior-level individuals describing their agreements to support those commitments.

Where appropriate, describe the shared facilities to be established including specific major research instruments and plans for the development of instruments. Describe plans for

maintaining and operating the facilities including staffing, provisions for user fees, and plans for ensuring access to outside users. Distinguish between existing facilities and those still to be developed.

7. Research Plan

A. Specific Aims – A BRP may propose design-directed, developmental, discovery-driven, or hypothesis-driven research. Thus, the application should state the hypotheses, designs, problems, and/or needs that will drive the proposed research. Describe the specific aims in the appropriate area of bioengineering research and the goals for the first year and for the long term. Describe the expected applications of the bioengineering research that will improve human health. One page is recommended.

B. Background and Significance - Briefly describe the area of bioengineering research that is the focus of the BRP. Critically evaluate existing knowledge and approaches that have been or are being applied in the area and specifically describe how the proposed BRP approach will advance the field. State concisely the importance and health relevance of the research proposed to achieve the Specific Aims.

C. Preliminary Studies and Rationale - Preliminary studies that support the proposed research should be described in the application.

D. Research Design and Methods - A BRP should focus on a systems approach in a significant area of bioengineering research. Describe an overall research plan that is sufficiently long term (five to ten years) to justify organizing a BRP and adaptable enough to permit change as the research proceeds. Clearly indicate current activities, why a BRP is necessary, and what unique opportunities will be provided by the proposed BRP. Explain the integrative-engineering approach and why such an approach is essential to the proposed research. If the proposed BRP research is closely related to ongoing research or an existing center, explain how the research activities of the BRP will complement but not overlap existing research. Describe the contributions of each partner and how these will be integrated and organized to accomplish the specific aims of the project. Provide a tentative sequence or timetable for the project. If appropriate to the project, state quantitative milestones corresponding to timetable events. Include a description of how the data will be collected, analyzed, and interpreted. Discuss major technical challenges and possible alternative approaches to achieve the aims. Describe plans for enhancing the abilities and opportunities for investigators and trainees to work across disciplinary boundaries.

8. Applications should include a plan for making available to the research community any technologies developed or enhanced by work conducted as part of the program announcement. This plan should be described in the Research Design and Methods section of the application. Investigators using PHS funds are required to make unique research resources readily available for research purposes to qualified individuals within the scientific community when the results have been published. The intent of this policy is not to discourage, impede, or prohibit the organization that develops the unique research resources or intellectual property from commercializing the products.

APPLICATION RECEIPT DATES: Applications submitted in response to this program announcement will be accepted on January 23, 2003, and August 22, 2003. These are the dates that applications must be received at the NIH.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the checklist, and five signed photocopies in one package to:

Center for Scientific Review
National Institutes of Health/DHHS
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

APPLICATION PROCESSING: Applications must be received by the date listed on the first page. If an application is received after that date, it will be returned to the applicant without review.

The CSR will not accept any application in response to this PA that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantial revision of an application already reviewed, but such application must include an Introduction addressing the previous critique.

PEER REVIEW PROCESS

Applications submitted for this PA will be assigned on the basis of established PHS referral guidelines. An appropriate scientific review group convened in accordance with the standard NIH peer review procedures (http://www.csr.nih.gov/refrev.htm) will evaluate applications for scientific and technical merit.

As part of the initial merit review, all applications will:

o Receive a written critique
o Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score
o Receive a second level review by the appropriate national advisory council or board

REVIEW CRITERIA

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to discuss the following aspects of your application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals:

o Significance
o Approach
o Innovation
o Investigator
o Environment

The NIH review criteria have been adapted to ensure that the BRP application is evaluated appropriately. The score should reflect the overall impact that the BRP award could have on the selected area of bioengineering research based on consideration of the five criteria given below. The emphasis on each criterion can vary from one application to another depending on the nature of the application and its relative strengths. An application need not be strong in all categories to be judged likely to have major technical or scientific impact and thus deserve a high priority score. For example, an investigative partnership may propose to perform important work that by its nature is not innovative but is essential to advance a field.

A BRP may propose design-directed, developmental, discovery-driven, or hypothesis-driven research at universities, national laboratories, medical schools, large or small businesses, or other public and private entities. The review criteria include:

1. Significance. If the specific aims of the BRP are achieved, will they provide significant advances in the selected area of bioengineering research?

Is the research likely to have a significant impact on other areas of research? Will the technological advances have a significant impact on human health?

2. Approach. Are the BRP engineering, scientific and clinical approaches and methods adequately developed, well integrated, and appropriate to the aims of the project? Does the application address potential problem areas and consider alternative strategies? Is a timetable with adequate research milestones proposed? Are appropriate specifications and evaluation procedures provided for assessing technological progress? Is the proposed partnership adequate for the research? Is the partnership strategy well-planned and documented? Is there evidence that the partners from academia or industry can work together effectively, have an impact on achieving the research goals, and disseminate the technology developed (including through commercialization)? Is the plan for sharing or disseminating technologies developed or enhanced under this program announcement adequate? Do they describe arrangements that facilitate the fruitful participation of a partner at a distant site? If partnership with industry or small business is included, does this positively affect the research goals and technology dissemination?

3. Innovation. Does the BRP propose new approaches, explore new research paradigms, or represent new concepts that combine engineering, physical, and clinical sciences? Will the proposed approaches or concepts solve current scientific or technical problems in novel ways?

4. Investigators. Is the PI capable of coordinating and managing the proposed BRP? Are the investigators (partners) appropriately trained in their disciplines and capable of conducting the proposed interdisciplinary work?

5. Environment. Does the scientific and technological environment in which the work will be done contribute to the probability of success? Does the proposed research take advantage of unique features of the scientific environment or employ useful collaborative arrangements within the partnership? Is there evidence of institutional support? Does the partnership create potential opportunities to foster trans-disciplinary communication and training across traditional scientific and technical boundaries?

ADDITIONAL REVIEW CRITERIA: In addition to the above criteria, your application will also be reviewed with respect to the following:

PROTECTIONS: The adequacy of the proposed protection for humans, animals, or the environment, to the extent they may be adversely affected by the project proposed in the application.

INCLUSION: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria included in the section on Federal Citations, below)

DATA SHARING: The adequacy of the proposed plan to share data.

BUDGET: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

AWARD CRITERIA

Applications submitted in response to a PA will compete for available funds with all other recommended applications. The following will be considered in making funding decisions:

o Scientific merit of the proposed project as determined by peer review
o Availability of funds
o Relevance to program priorities

REQUIRED FEDERAL CITATIONS

MONITORING PLAN AND DATA SAFETY AND MONITORING BOARD: Research components involving Phase I and II clinical trials must include provisions for assessment of patient eligibility and status, rigorous data management, quality assurance, and auditing procedures. In addition, it is NIH policy that all clinical trials require data and safety monitoring, with the method and degree of monitoring being commensurate with the risks (NIH Policy for Data Safety and Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the AMENDMENT "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html);
a complete copy of the updated Guidelines are available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.
The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS:
The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at http://grants.nih.gov/grants/funding/children/children.htm.

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

HUMAN EMBRYONIC STEM CELLS (hESC): Criteria for federal funding of research on hESCs can be found at http://grants.nih.gov/grants/stem_cells.htm and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. Only research using hESC

lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see http://escr.nih.gov).
It is the responsibility of the applicant to provide the official NIH identifier(s)for the hESC line(s)to be used in the proposed research. Applications that do not provide this information will be returned without review.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT: The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople.

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance Nos. 93.286, 93.287, 93.394, 93.395, 93.396, 93.306, 93.867, 93.172, 93.837, 93.838, 93.839, 93.866, 93.273, 93.855, 93.856, 93.846, 93.864, 93.865, 93.929, 93.279,

93.173, 93.121, 93.847, 93.848, 93.849, 93.113, 93.821, 93.859, 93.862, 93.242, 93.853, 93.361, and 93.879. Awards are made under authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and administered under NIH grants policies described at http://grants.nih.gov/grants/policy/policy.htm and Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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